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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,215	01/22/2001	John Bertin	07334-142001/ MPI2000-003	3061

26161 7590 08/26/2003

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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	17

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/767,215	Applicant(s) BERTIN, JOHN	
	Examiner MINH-TAM DAVIS	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 21-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2 and 32* is/are allowed.

6)☒ Claim(s) *21-31, 33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 3-20, and adds new claims 35-40, which are related to claims 1-8, 21-34 and are not new matter.

Accordingly, claims 1-2, 21-40 are being examined.

Claims 1-2, 32 seem to be free of prior art, and are allowable.

The following are the remaining rejections.

OBJECTION

The specification is objected to because it contains blank spaces, e.g. blank spaces after ATCC on pages 7-9.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Rejection under 35 USC 112, first paragraph of claims 21-28, 33-34, pertaining to lack of a clear written description of an isolated polypeptide comprising a fragment of SEQ ID NO:2, or a polypeptide that is at least 85%, 95%, 98% identical to SEQ ID NO:2, wherein said polypeptide binds to Bcl-10, remains for reasons already of record in paper No.15. New claims 35-37 are rejected for the same reasons already of record.

Applicant argues as follows:

(i) Polypeptidess containing a specific functional domain of CARD-14

Applicant argues that the precise structural definition of the polypeptides of claims 21-25, 33,34. comprising amino acid residues that correspond to the CARD, coiled coil domain, PDZ domain, SH3 domain, or GUK domain of the claimed CRD-14, allows the skilled artisan readily envision the claimed invention. Applicant asserts that the polypeptides of claims 21-25 are described in the specification, and a working example of a polypeptide containing the CARD of CARD-14 is described in the specification at page 20, lines 10-31, demonstrating that a polypeptide containing the CARD of CARD-14 binds specifically to the CARD of Bcl-10.

Applicant further argues that because the claimed polypeptides contain a particular functional domain of CARD-14, the polypeptide necessarily retain the functional activity present in the recited portion of CARD-14. Applicant argues that polypeptides containing such functional regions of CARD-14 can be used for example in screening for compounds that modulate a CARD-14 activity associated with that particular region.

(ii) Percent identity

Applicant argues that the genus of the polypeptides encompassed by claims 26-28 does not have substantial variation, since all such polypeptides must have a specified activity and contain an amino acid sequence that has at least 85% identity with SEQ ID NO:2. Applicant argues that the specification discloses assays for identifying polypeptides that binds to Bcl-10. Applicant asserts that binding to Bcl-10 is a function of the polypeptide. Applicant asserts that some proteins contain a binding domain that is responsible for binding to a target protein as well as a catalytic domain that carries out a

catalytic function only after a binding event has taken place. Applicant asserts that the ability of an antibody to bind to target antigen is a biological function of the antibody. Applicant asserts that binding of CARD-14 to Bcl-10 is a requisite step in the triggering of cell signaling processes that result from the CARD-14-Bcl-10 protein-protein interaction.

Applicant's arguments set forth in paper No.16 have been considered but are not deemed to be persuasive for the following reasons:

(i) Polypeptides containing a specific functional domain of CARD-14

Contrary to Applicant's assertion, the precise structure of the claimed polypeptides comprising a domain of the CARD-14 is not disclosed in the specification. Only a single species of the claimed genus is described in the specification, i.e. the claimed CARD-14 of SEQ ID NO:2. The claims 21-25 and dependent claims 33-34 encompass unrelated polypeptides of any structure and function, provided they contain a domain of CARD-14. It is noted that an example on page 20, lines 10-31 only discloses that a polypeptide fragment consisting of amino acids 1-118 of SEQ ID NO:2 containing a CARD domain is used for screening compounds that binds to said fragment, i.e. Bcl-10. There is no working example of how to make or use polypeptides of any structure and function, provided they contain a domain of CARD-14.

(ii) Percent identity

Contrary to Applicant arguments, binding to Bcl-10 per se is only a physical property and not a function of the claimed polypeptides. Although binding to Bcl-10 is a requisite step in the triggering of cell signaling processes that result from the CARD-14-

Bcl-10 protein-protein interaction, binding to Bcl-10 per se is not sufficient for triggering of cell signaling processes.

Further, concerning an example of antibody recited by Applicant, this example is not applicable to the claimed invention, because the structure and properties of the antibody is known via its binding to an antigen, i.e. the structure and properties of the antibody CDRs binding regions are based on the antigen to which the antibody is bound, whereas the structure of the claimed polypeptide could not be deduced or assessed based on binding alone to Bcl-10, i.e. the claimed polypeptides encompass unrelated polypeptides with unknown structure, provided it encompasses a CARD fragment of the claimed CARD-14, wherein said CARD fragment provides the binding property to Bcl-10.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE OF ENABLEMENT

Claims 26-28 remain rejection under 35 USC 112, first paragraph, pertaining to lack of enablement for a polypeptide that is at least 85%, 95%, 98% identical to SEQ ID NO:2, wherein said polypeptide binds to Bcl-10, remains for reasons already of record in paper No.15.

Claims 21-15, 29-31, 33-40 are rejected for the same reasons already of record.

It is note that claims 21-15, 29-31, 33-40 were inadvertently omitted from the previous rejection. It is clear that claims 21-15, 29-31, 33-40 should have been included in the rejection, because the same issue is involved in the rejection.

Applicant argues that the one could use the Bcl-10 binding polypeptides to screen and identify compounds that inhibits the CARD-14-Bcl-10 interaction and thereby block cell signaling processes that result from the interaction. The specification discloses how to carry out such screens.

Applicant's arguments set forth in paper No.16 have been considered but are not deemed to be persuasive for the following reasons:

Concerning the claimed polypeptide variants of SEQ ID NO:2 that bind to Bcl-10, Applicant has not shown how to make such variants. Applicant has not shown how to make the claimed variants that do not include the CARD domain, or how to change 3%, 5% or 15% at any amino acid position of SEQ ID NO:2 and still result in a polypeptide that binds to Bcl-10.

Concerning claims 21-25 and dependent claims 33-34, 35-37, Applicant has not shown how to make the claimed polypeptides with any structure and function, wherein said polypeptides comprise a fragment of SEQ ID NO:2.

Concerning claims 29-31, and 38-40, drawn to polypeptide variants of SEQ ID NO:2, that activates NF-kB or stimulate phosphorylation of Bcl-10, Applicant has not shown how to make such variants. Applicant has not shown how to change 3%, 5% or 15% at any amino acid position of SEQ ID NO:2 and still result in a polypeptide that activates NF-kB or stimulates phosphorylation of Bcl-10.

Protein chemistry however is unpredictable, wherein change of a single amino acid could often dramatically affect the biological activity and characteristics of a protein, as taught by Burgess et al, Lazar et al, Tao et al and Gillies et all, all of record.

Therefore, it would be undue experimentation for one of skill in the art to make the claimed invention. Thus the contemplation of using such polypeptides for screening compounds that inhibits the CARD-14-Bcl-10 interaction and thereby block cell signaling processes that result from the interaction would not obviate this rejection, since one would not know how to make such polypeptides for use as contemplated in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

August 22, 2003